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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/518,478 | 07/26/2005 | Andrew McLellan | Q85433 | 5575 |
| 23373 | 7590 | 12/29/2008 | EXAMINER | |
| SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037 | | | MIRABEAU, MONIQUE A | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/518,478 | Applicant(s) MCLELLAN ET AL. | |
| | Examiner MONIQUE MIRABEAU | Art Unit 1797 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 December 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/26/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Summary

1. This is the initial Office action based on the 10/518, 478 application filed July 26, 2005.
2. Claims 1-26 are pending and have been fully considered.

Priority

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p) (5) because they include the following reference character(s) not mentioned in the description: Figure 20b, reference number 64. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required

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corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

5. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the one or more coatings must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

6. The specification is objected to as failing to provide a reference to the PCT in the first paragraph of the specification. Appropriate correction is required.

Claim Objections

7. Claim 7 is objected to because of the following informalities: claim 7, line 1 recites "any one of" which appears to be a grammatical error and should be amended. Appropriate correction is required.

8. Claims 11-12 are objected to because of the following informalities: as being dependent on a rejected base claim, but would be allowable if re-written to include all the limitations of their base claim. Appropriate correction is required.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 1 - 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens et al. (US 5, 605, 813) in view of Oberhardt (US 4, 849, 340).

12. With respect to claim 1, Stevens et al. teaches a base member (12) (body) defining a receptacle (14) (cavity), for positioning over the substrate to form a receptacles (14) (reaction chamber); and a lever (16) (projection) extending from the base member (12) (body) (fig. 1). Stevens et al. does not specifically define a fluid reservoir being in fluid communication with the cavity.

13. However, Oberhardt teaches a sample well (64, fig.14) (fluid reservoir) being in communication (fluid communication) with the reaction volume (66, fig. 13, fig. 14) (cavity) (col. 13, lines 30-35; col. 6, lines 23-29). It would have been obvious to one of ordinary skill in the art to modify the device of Stevens to provide a sample well (fluid reservoir) in communication with the receptacle (cavity) in order to in order to provide a separate introduction point for sample so that it could be treated, such as by filtering) prior to introduction to the cavity.

14. With respect to claim 2, modified Stevens et al. teaches a lid (18) (cover) wherein the receptacle (14) (cavity) extends the full width of the receptacle chamber (14) (sample holding region) of the base member (12) (substrate) (fig. 2).

15. With respect to claim 3, modified Stevens et al. teaches the lid (18) (cover) wherein a lever (16, 52, 54, 56) (protrusion extends from the projection) to assist in wicking fluid into the receptacle (14) (reservoir) (col. 3, lines 27-29, 41-49, 55-67; fig. 1, fig. 4).

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16. With respect to claims 4 - 5, Stevens et al. does not specifically teach the reservoir being defined by a first section, angled at least at substantially 60° relative to the cavity, and a second section, positioned between the cavity and the first section, and oriented at a reduced angle relative to the cavity, as compared to the first section; the second section is angled at least at substantially 15°. However, Oberhardt teaches the sample receiving opening (112) (reservoir/first section) angled at 90° (least at 60°) relative to the conduit (114) (cavity), and at the point where the sample receiving opening (112) and the conduit (114) meet (second section) positioned between the conduit (114) (cavity) and the sample receiving opening (112) (first section), and oriented at a reduced angle relative to the conduit (114) (cavity), as compared to the sample receiving opening (114) (first section) (fig. 15). The conduit (114) (second section) is angled at least at substantially 15° (fig. 15). It would have been obvious to one of ordinary skill in the art to modify the device of Stevens et al. to provide the first section angled at least at substantially 60° relative to the conduit, and the second section oriented at a reduced angle relative to conduit as taught by Oberhardt to release the bubbles in the flow fluid.

17. With respect to claims 6 - 10, Stevens et al. teaches a receptacle (14) with a lid (18) (cover) preferably formed from transparent polymer materials, such materials include, but not limited to , polystyrene, polypropylene, celluloid, polymethacrylate and polymethylmethacrylate (col. 3, lines 20-26). Stevens et al. does not specifically teach the cavity includes a coating with reduced porosity or to reduce surface roughness of the polymer. It is well known in the art to provide coatings within test device reaction

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chambers in order to adjust the surface properties of the polymer used, such as increase hydrophilicity or hydrophobicity. It would have been obvious to one of ordinary skill in the art to coat the interior of the receptacle and lid of Stevens et al. in order to increase the hydrophilicity, and consequently decrease the surface roughness and porosity of the polymer material.

18. With respect to claim 13, modified Stevens et al. teaches a lid (18) (cover) wherein the width of the cavity of the lid (18) (cover) is no longer than the width of a base member (12) (microscope slide) (fig. 1).

19. With respect to claim 14, Stevens et al. does not specifically teach the cavity is substantially planar. However, Oberhardt teaches a cover (10) wherein the overlay (20) (cavity) is substantially planar (fig. 2, fig. 4). It would have been obvious to provide a smaller, planar receptacle within the device of Stevens, et al. in order to employ a smaller amount of sample, culture media, etc. to reduce consumption and provide for quicker results of the test.

20. With respect to claim 15, Stevens et al. teaches a locator (54) for controlling and locating the cover.

21. With respect to claim 16, Stevens et al. does not specifically teach a second reservoir, at an opposite end of the cover. However, Oberhardt teaches a reaction volume (66) (second reservoir), at the opposite end of the cover (10) (fig. 6). It would have been obvious to modify Stevens, et al. to provide a second reservoir for introduction of a second reagent for the culture/analysis.

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22. With respect to claims 17 - 21, it would appear that the device of Stevens et al. includes the wall portions located at the edge of the cover, surrounding the cavity on two or more sides (Figure 1). Stevens et al. teaches the legs extending along the sides of the cavity to form the wall portions. Stevens et al. teach the lid (18) (cover) is supported upon the base member (12) (substrate) on the sidewalls (40) (wall portions) (fig. 2).

23. With respect to claim 22, Stevens et al. teaches the bottom surface (48) is removably attached to surface (20) of the base member (12) (col. 3, lines 27-29). Manual force is applied to the working end toward the upper surface of the base so that the pivot position contacts the upper surface of the base, allowing the working end of the lever to exert force on the flange and bottom surface of the chamber in an upward direction so as to disengage the chamber from the base, with the receptacle being removed (col. 3, lines 41-49), allowing the sample to be cleared (col. 3, lines 55-67; col. 4, lines 1-5). It appears the device of modified Stevens et al. is capable of allowing the cover to be engaged and pivoted relative to the substrate so as to open the reaction chamber and allow the slide to be cleared of fluid.

24. With respect to claim 23, modified Stevens et al. teaches the cavity of the lid (18) (cover) is arranged to face the base member (12) (substrate) so as to form a receptacle (14) (reaction chamber) (fig. 1).

25. With respect to claim 24, it would have been obvious to one of ordinary skill in the art to employ the modified device of Stevens et al. to treat a sample including depositing fluid into the sample receiving opening (112) (fluid reservoir) to allow the fluid

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to be drawn to the conduit (114) (reaction chamber) (col. 14, lines 13-18). It would have been obvious to one having ordinary skill in the art to have the fluid sucked into the conduit Oberhardt in order to take advantage filling the conduit completely with fluid.

26. With respect to claim 25, modified Stevens et al. does not specifically teach varying the reaction chamber volume. However, it is well known to those of ordinary skill in the art to vary the volume in the reaction chamber due to application varying specifications for the fluid. It would have been obvious to one of ordinary skill in the art to vary the volume in the modified device of Stevens et al. in order to remove an excess sample from the receptacle.

27. With respect to claim 26, Stevens et al. teaches removing (sliding) the lid (118) (cover) relative to the base member (12) (substrate) until the lid (18) (cover) is engaged and lifted relative to the base member (12) (substrate) to pivot the lid (18) (cover) to an open condition, allowing the sample (fluid) to be cleared (drained) (col. 3, lines 55-67; col. 4, lines 1-5).

Conclusion

28. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The reference Chikakiyo et al. (JP 63-079532) discloses an observation plate.

The reference Miller (UK 2 127 577) discloses a wet-mount microscopic examination slide.

The reference Del Buono (US 6, 118, 582) discloses a slide holder.

The reference Chiarin et al. (US 6, 594, 077) discloses a slide for the microscopic examination of biological fluids.

The reference Nason (US 4, 790, 640) discloses a laboratory slide.

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONIQUE MIRABEAU whose telephone number is (571) 270-5543. The examiner can normally be reached on M-F, alternate F off (8am-4pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JILL WARDEN can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

Monique Mirabeau

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797